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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/738,912	12/16/2003	Herman E. Snyder	PAT053285-US-CNT	8356
1095	7590	06/11/2010		
NOVARTIS CORPORATE INTELLECTUAL PROPERTY ONE HEALTH PLAZA 101/2 EAST HANOVER, NJ 07936-1080			EXAMINER BOECKMANN, JASON J	
			ART UNIT 3752	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/738,912	<b>Applicant(s)</b> SNYDER ET AL.	
	<b>Examiner</b> Jason J. Boeckmann	<b>Art Unit</b> 3752	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 26,28,30-32,40-45,47 and 51 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 26,28,30,32,40-45,47 and 51 is/are rejected.
- 7) ☒ Claim(s) 31 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 40 and 43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 40 recites the limitation "the pharmaceutical liquid" in line 1. There is insufficient antecedent basis for this limitation in the claim. It is noted that not only does claim 26 not positively claim a pharmaceutical liquid, it only refers to a liquid flow channel (line 3), and never positively recites a liquid, or that liquid flows through the liquid flow channel.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

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the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 26, 28, 30, 32, 40-45, 47 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Platz et al. (6,051,256), in view of Watanabe et al. (5,845,846).

Platz et al. shows a spray drying system that includes an atomizer (57) to create fine liquid droplets, a drying chamber (50) to dry the droplets to form particles; and a collector (76) to collect the particles, but does not that the atomizer includes a first liquid flow channel the first liquid flow channel comprises a constriction that has a diameter of less than .1mm for spreading the liquid into a thin film in the channel, the atomizer further comprising first and second gas flow channels through which an atomizing gas flows, wherein the first liquid flow channel is intermediate to the first and second channel gas flow channels and the first and second gas flow channels being positioned so that the atomizing gas impinges the liquid thin film to produce droplets.

However, Watanabe et al. shows a system including an atomizer, the atomizer comprising a first liquid flow channel (the channel to outlet 105), the first liquid flow channel comprises a constriction (at outlet 105) that has a diameter for spreading the liquid into a thin film in the channel, the atomizer further comprising first and second gas

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flow channels (1015, 1014) through which an atomizing gas flows, wherein the first liquid flow channel is intermediate to the first and second channel gas flow channels (fig10) and the first and second gas flow channels being positioned so that the atomizing gas impinges the liquid thin film to produce droplets, but does not specifically disclose that the diameter of the constriction is less than .51mm (or .1mm for claims 29 and 47), or that the system includes a drying chamber to dry the droplets to form particles; and a collector to collect the particles.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to use the atomizer of Watanabe et al. instead of the atomizer of Platz et al., in the system of Platz, in order to eject the liquid as extremely minute particles, as taught by Watanabe et al (col 1, lines 5-10).

The system of Platz as modified by Watanabe et al. above still fails to disclose that the constriction that has a diameter of less than .1mm

However, it would have been obvious to one with ordinary skill in the art at the time the invention was made to make the diameter of the constriction less than .1 mm since our reviewing courts have held that where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device.

*Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984).

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Additionally, it is noted that Watanabe et al. teaches that the liquid is ejected into fine particles of 1 micron to 5 microns in diameter (col 9, lines 18-21). In order for the liquid to be ejected particles of these diameters, the liquid nozzle outlet must be of a similar size. It is also well known in the art that the smaller the constriction, the faster the fluid velocity will be going through the restriction, as well as the more turbulent it will be.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to make the constriction diameter less than .1mm in diameter, in order to increase the velocity and the turbulence of the fluid as it passes

Regarding claim 30, the liquid flow channel and the second gas flow channel (1014) are annular and the first gas flow channel is circular (1015) (fig 10).

Regarding claim 32, the system of Platz et al. as modified by Watanabe et al. above, shows all aspects of the applicant's invention as in claim 26 above, but fails to specifically disclose that the drying chamber has a gas outlet having an outlet temperature of 50 degrees Celsius.

However, it is well known that the hotter the gas in the drying chamber, the quicker the particles in the chamber will dry. The drying chamber of Platz includes a gas inlet channel including a heater (65) that heats the gas in the drying chamber to a specific temperature so that the gas leaving the chamber (in tube 70) is at a specific temperature.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to set the heater so that the gas stream leaving the

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drying chamber is above 50 degrees Celsius, since it has been held that discovering an optimum values of a results effective variable involves only routine skill in the art.

Additionally, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to set the heater so that the gas stream leaving the drying chamber is above 50 degrees Celsius, in order to dry the liquid particles into a fine powder at a faster rate than if it were set to a lower temperature.

Regarding claims 40 and 43, the liquid used in the device of Platz includes an active ingredient (column 8, line 60) and an excipient (column 9, line 35). Additionally, it is noted that MPEP 2115 states that the material worked upon in an apparatus claim does not limit the claim. See MPEP 2115. Therefore, the fact that the liquid has an active ingredient and an excipient that has a glass transition temperature of 35 degrees Celsius does not further limit the apparatus. The device of Platz et al. as modified by Watanabe et al. is fully capable of being used with such a fluid.

Regarding claims 41, 44 and 51, Platz teaches that the particle that are produced by his system have a rugosity above 2 (column 6, line 2) and a particle size of less than 10 microns.

Regarding claim 42, the system of Platz et al. as modified by Watanabe et al. shows all aspects of the applicant's invention as in the rejection of claim 26 above, but fails to specifically disclose that the particles have a density of less than  $.5\text{g/cm}^3$ .

However, it is known that the density of the finished particles is determined by the type of liquid used, and the amount of drying that takes place in the drying chamber.

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The heavier the liquid, the higher the density, and the hotter and the longer the particles are dried, the lower the density.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to use a material that makes the particles have a density of less than  $.5\text{g/cm}^3$ , and dry the particles so that the density is less than  $.5\text{g/cm}^3$  since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use of the device.

Additionally, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to make the particles have density of less than  $.5\text{g/cm}^3$  by either choosing the right material, or drying them to evaporate enough water, in order to produce particles that are light enough to be entrained in the air for a patient to breathe.

Regarding claim 45, the channels are concentric.

### ***Allowable Subject Matter***

Claim 31 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.



***Response to Arguments***

Applicant's arguments with respect to claims 26, 28, 30-32, 40-45, 47 and 51 have been considered but are moot in view of the new ground(s) of rejection.

See the modified 103 rejections above of Platz in view of Watanabe et al..

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason J. Boeckmann whose telephone number is

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(571)272-2708. The examiner can normally be reached on 8:00- 5:00, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Len Tran can be reached on (571) 272-1184. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jason J Boeckmann/  
Examiner, Art Unit 3752  
6/7/2010